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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/059,521	01/29/2002	Ivan N. Rich	R103 1030.1	5794

7590 10/19/2004
Womble Carlyle,
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P.O. Box 7037
Atlanta, GA 30357-0037

EXAMINER

GABEL, GAILENE

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 10/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/059,521

Applicant(s)

RICH, IVAN N.

Examiner

Gailene R. Gabel

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 January 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-56 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-56 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-28, drawn to method of determining the proliferative status of a cell population, classified in class 436, subclass 63, for example.
 - II. Claims 45-49, drawn to method for identifying primitive hematopoietic cells for transplant, classified in class 435, subclass 2, for example.
 - III. Claims 50-56, drawn to screening a compound that modulates proliferation of hematopoietic cells, classified in class 436, subclass 172, for example.

The inventions are distinct, each from the other because of the following reasons:

Inventions I, II, and III are independent and distinct. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation, different functions, and different effects in that in Group I, a cell population is incubated with growth medium then contacted with reagent label to detect for luminescence; in Group II, is incubated with growth medium and a cytokine, then contacted with a reagent label to detect for luminescence indicative of transplant suitability; and in Group III, two target cell populations are contacted with a test

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compound to detect for and compare differential modulation of proliferative status between the two cell populations by the test compound.

2. This application also contains claims 29-41, directed to the following patentably distinct species of Group I:

1) stem cell factor, IL-7, or Flt3L generating CFC-Blast stem cells;

2) macrophage CSF, IL-1, IL-3, IL-6, or stem cell factor generating HPP-CFC stem cells;

3) erythropoietin, granulocyte-macrophage CSF, granulocyte CSF, stem cell factor, IL-3, IL-6, or Flt3L generating hematopoietic CF cell erythroid, and macrophage or megakaryocyte CFC-GEMM stem cells;

4) erythropoietin, erythropoietin and IL-3, erythropoietin and stem cell factor, or erythropoietin and stem cell factor, or erythropoietin, stem cell and il-3 generating hematopoietic BFU-E progenitor cells;

5) granulocyte-macrophage CSF, granulocyte-macrophage CSF and IL-3, or granulocyte-macrophage CSF, IL-3, and stem cell factor generating hematopoietic granulocyte-macrophage (GM-CFC) progenitor cells;

6) thrombopoietin or thrombopoietin and IL-3 and IL-6 generating hematopoietic CFC-Mega progenitor cells;

7) IL-2 and IL-7 or Flt3L and IL-5 generating hematopoietic B-CFC progenitor cells;

8) erythropoietin generating hematopoietic CFU-E progenitor cells;

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9) granulocyte CSF or granulocyte-macrophage CSF generating hematopoietic (G-CFC) progenitor cells;

10) IL-3 or IL-3 and stem cell factor generating hematopoietic CFC-Bas progenitor cells;

11) granulocyte-macrophage CSF, IL-3, or IL-5 generating hematopoietic CFC-Eo progenitor cells;

12) macrophage CSF, macrophage CSF and granulocyte-macrophage CSF, or IL-7 and granulocyte-macrophage CSF generating hematopoietic macrophage (M-CFC) progenitor cells.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-28 and 42-56 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper. Furthermore, because the search required for Group I and its individual species is not required for Group II, and the search for Group II is not required for Group III, restriction for examination purposes as indicated is proper. Literature search for each of the methods is distinct since the structural requirements of each invention are different. While searches would be expected to overlap, there is no reason to expect the searches to be coextensive.

4. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gailene R. Gabel whose telephone number is (571)

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272-0820. The examiner can normally be reached on Monday, Tuesday, and Thursday, 7:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gailene R. Gabel
Patent Examiner
October 1, 2004 *GG*

Christopher L. Chin
CHRISTOPHER L. CHIN
PRIMARY EXAMINER
GROUP ~~1800~~ 1641
10/15/04